# IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

RUTH SMITH, Individually and as Widow	)
for the Use and Benefit of Herself and the	)
Next of Kin of RICHARD SMITH, Deceased,	Case #: 3:05-00444 Judge Trauger
Plaintiff,	)
-against-	)
PFIZER INC., PARKE-DAVIS,	)
a division of Warner-Lambert Company	)
and Warner-Lambert Company LLC,	)
WARNER-LAMBERT COMPANY,	)
WARNER-LAMBERT COMPANY LLC and	)
JOHN DOE(S) 1-10,	)
	)
Defendants.	)

## PLAINTIFF'S RESPONSE TO DEFENDANTS' OBJECTIONS TO THE PROPOSED STATEMENT OF PLAINTIFF'S EXPERT RONALD WM. MARIS, PH.D.

Plaintiff Ruth Smith, as the Widow for the use and benefit of herself and the next of kin of Richard Smith, deceased, by and through her attorneys, hereby submits Plaintiff's Response to Defendants' Objections to the Proposed Statement of Plaintiff's Expert Ronald Wm. Maris, Ph.D.

Testimony	Objection	Response
Unnumbered Introductory	• Irrelevant (FRE 401,	Introductory remarks. Explains
Paragraph – "You may be	402)	potential confusion between
wondering if I am related to		Roger Maris and Ronald Maris.
former Yankee and St. Louis		
baseball player, Roger Maris.		
The short answer is 'yes,'		
distantly. He and I were the		
same age and I went to the		
University of Illinois on a		
track and basketball		
scholarship."		

Testimony	Objection	Response
¶ 1, n.1 – "Neurontin affects the neurotransmitter Serotonin, which can make a person more suicidal"	• Foundation, witness lacks knowledge, skill, experience, training, or education sufficient to render opinion (FRE 702)2	Defendant's identical objections have previously been overruled by Judge Saris in her Daubert opinion.
All of ¶ 2, entitled "Prescription Drugs Can Cause Suicides."3	<ul> <li>Irrelevant (FRE 401, 402)</li> <li>Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury (FRE 403)</li> <li>Improper propensity evidence (FRE 404(b)4</li> <li>Not helpful to trier of fact (FRE 702)</li> <li>Improper opinion not previously disclosed (FRCP 26(a)(2)(B) and 37(c)(1))5</li> </ul>	Opinion was disclosed on page 6 of his expert report detailing his testimony in other suicide litigations. Further, Defendants deposed Dr. Maris on his work in the Columbia University/FDA Reclassification Study. See p. 30, deposition 9/29/2008. Opinion directly counters opinion of defense expert Douglas Jacobs who testifies that no pharmaceutical product can cause suicides.
¶ 2 – "In the past 10 years, it has become clear that many prescription drugs can cause suicides."	<ul> <li>Irrelevant (FRE 401, 402)</li> <li>Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury (FRE 403)</li> <li>Improper propensity evidence (FRE 404(b))</li> <li>Not helpful to trier of fact (FRE 702)</li> <li>Improper opinion not previously disclosed (FRCP 26(a)(2)(B) and 37(c)(1))</li> </ul>	Opinion was disclosed on page 6 of his expert report detailing his testimony in other suicide litigations. Further, Defendants deposed Dr. Maris on his work in the Columbia University/FDA Reclassification Study. See p. 30, deposition 9/29/2008. Opinion directly counters opinion of defense expert Douglas Jacobs who testifies that no pharmaceutical product can cause suicides.

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¶ 2 – "This research group concluded that antidepressant drugs were linked to suicides in adolescents and children."	<ul> <li>Irrelevant (FRE 401, 402)</li> <li>Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury (FRE 403)</li> <li>Improper propensity evidence (FRE 404(b))</li> <li>Not helpful to trier of fact (FRE 702)</li> <li>Improper opinion not previously disclosed (FRCP 26(a)(2)(B) and 37(c)(1))</li> </ul>	Opinion was disclosed on page 6 of his expert report detailing his testimony in other suicide litigations. Further, Defendants deposed Dr. Maris on his work in the Columbia University/FDA Reclassification Study. See p. 30, deposition 9/29/2008. Opinion directly counters opinion of defense expert Douglas Jacobs who testifies that no pharmaceutical product can cause suicides.
¶ 2 – "The FDA adopted these conclusions and anti-depressants today carry a suicide warning."	<ul> <li>Irrelevant (FRE 401, 402, 407)</li> <li>Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury (FRE 403)</li> <li>Improper propensity evidence (FRE 404(b)) Not helpful to trier of fact (FRE 702)</li> <li>Improper opinion not previously disclosed (FRCP 26(a)(2)(B) and 37(c)(1))</li> </ul>	Opinion was disclosed on page 6 of his expert report detailing his testimony in other suicide litigations. Further, Defendants deposed Dr. Maris on his work in the Columbia University/FDA Reclassification Study. See p. 30, deposition 9/29/2008. Opinion directly counters opinion of defense expert Douglas Jacobs who testifies that no pharmaceutical product can cause suicides.

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¶ 2 – "Given this relatively recent data, it is clear that some prescription drugs are also risk factors for suicide."	<ul> <li>Irrelevant (FRE 401, 402) Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury (FRE 403)</li> <li>Improper propensity evidence (FRE 404(b))</li> <li>Not helpful to trier of fact (FRE 702)</li> <li>Improper opinion not previously disclosed (FRCP 26(a)(2)(B) and 37(c)(1))</li> </ul>	Dr. Maris was deposed for over 150 pages on risk factors for suicide. See pp. 275 to 520, deposition 9/30/2008. In addition, Dr. Maris has been deposed on the FDA Statistical Review as well as the two recent epidemiological studies that form the basis of his conclusion that Neurontin is a risk factor for suicide.
The heading of ¶ 3, entitled "Neurontin is a Powerful Mood-Altering Drug."6	<ul> <li>The heading is argumentative and not supported by the body of the paragraph</li> <li>Foundation, insufficient facts or data, unreliable principles and methods (FRE 702)</li> <li>Foundation, witness lacks knowledge, skill, experience, training, or education (FRE 702)7</li> </ul>	Defendant's identical objections have previously been overruled by Judge Saris in her Daubert opinion. Dr. Maris discussed the psychopharmacologic properties of Neurontin in his report at p. 12.
¶ 3 – "The drug was designed to work by changing the levels of neurotransmitters in the brain."	• Foundation, witness lacks knowledge, skill, experience, training, or education (FRE 702)8	Defendant's identical objections have previously been overruled by Judge Saris in her Daubert opinion.

Testimony	Objection	Response
All of ¶ 4, entitled "FDA Concluded in 2008 that Neurontin Was Linked to Suicides."	<ul> <li>Misstates facts</li> <li>Hearsay (FRE 802)         Foundation, insufficient facts or data, unreliable principles and methods (FRE 702)9     </li> </ul>	"Misstates facts" is not an evidentiary objection. Pfizer's interpretation of the FDA's conclusions is properly the subject of cross-examination and not exclusion. Dr. Maris did NOT misstate facts. The FDA mandated a suicide warning on Neurontin in 2008. Defendant's identical objections have previously been overruled by Judge Saris in her Daubert opinion.
Exhibit 3849 (referenced in ¶ 4)	<ul> <li>Irrelevant (FRE 401, 402, 407)</li> <li>Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury (FRE 403)</li> <li>New Warning</li> <li>Rule of Completeness</li> </ul>	The FDA's initial warning to the medical community linking Neurontin to suicide is highly probative to the issue of general causation. This document is the type of document reasonably relied upon by experts in forming opinions or inferences. (FRE 703)
Exhibit 2018 (referenced in ¶ 5)	<ul> <li>Irrelevant (401, 402, 407)</li> <li>Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury (FRE 403)</li> <li>Hearsay (FRE 802)</li> </ul>	The FDA mandated suicide warning re: Neurontin is highly probative to the issue of general causation. This document is the type of document reasonably relied upon by experts in forming opinions or inferences. (FRE 703)

Testimony	Objection	Response
All of ¶ 6, entitled "Neurontin Can Cause Suicides."	<ul> <li>Foundation, insufficient facts or data, unreliable principles and methods (FRE 702)</li> <li>Foundation, witness lacks knowledge, skill, experience, training, or education (FRE 702)</li> <li>Hearsay, hearsaywithin-hearsay (FRE 802, 805)</li> <li>Misstates the facts</li> </ul>	Defendant's identical objections have previously been overruled by Judge Saris in her Daubert opinion.
Exhibit 460 (referenced in ¶ 6)	• Hearsay, hearsay- within-hearsay (FRE 802, 805)	This scientific study is the type of document reasonably relied upon by experts in forming opinions or inferences. (FRE 703)
¶ 6 – Testimony that study discussed in Exhibit 5869 "basically replicated the findings of the FDA that all anti-epileptic drugs generally increase the risk of suicide."	<ul> <li>Foundation, insufficient facts or data, unreliable principles and methods, given that study did not find statistically significant increase in suicide risk for Neurontin (FRE 702)</li> <li>Foundation, witness lacks knowledge, skill, experience, training, or education (FRE 702)</li> <li>Misstates facts</li> </ul>	Defendant's objections to this independent scientific peer-reviewed study focusing on suicide risk of Neurontin and other anti-epileptic drugs clearly constitutes "relevant evidence." FRE 401 & 402. Defendant's identical objections have previously been overruled by Judge Saris in her Daubert opinion. This scientific study is the type of document reasonably relied upon by experts in forming opinions or inferences. (FRE 703)

Testimony	Objection	Response
Exhibit 5870 (referenced in ¶ 6) and discussion related to it  ¶ 6 – "Neurontin (or	Hearsay, hearsay- within-hearsay (FRE 802, 805)	Defendant's objections to this independent scientific peer-reviewed study focusing on suicide risk of Neurontin and other anti-epileptic drugs clearly constitutes "relevant evidence." FRE 401 & 402. Defendant's identical objections have previously been overruled by Judge Saris in her Daubert opinion. This scientific study is the type of document reasonably relied upon by experts in forming opinions or inferences. (FRE 703)
gabapentin) increases a neurotransmitter in the brain called GABA. This increase in GABA, in turn, decreases brain chemicals (most notably monoamines like serotonin and norepinephrine). A decrease in serotonin (and serotonergic dysfunction in general) has been linked to suicidal behavior, especially for modern anti-depressantt drugs (such as the 9 studied for the FDA and Columbia University). This interaction of GABA and serotonin is one likely explanation of the link between Nuerontin and suicide."	facts or data, unreliable principles and methods (FRE 702)  Foundation, witness lacks knowledge, skill, experience, training, or education sufficient to render opinion (FRE 702)10	have previously been overruled by Judge Saris in her Daubert opinion.

Testimony	Objection	Response
All of ¶ 9, entitled "Richard Smith Was Taking Neurontin When He Committed Suicide."	• Not appropriate expert testimony because issue of whether Richard Smith was actually taking Neurontin is not outside the scope of knowledge and experience of the jury in weighing the evidence (FRE 702)	Ironically, Defendant fails to recognize that this identical topic was addressed at length in each of their three specific causation expert witness statements. Defendant's motion for summary judgment on this issue has been previously denied by this Court.
¶ 10 – "Significantly, several of these risk factors (depression, suicidal thoughts, and hopelessness) were triggered and/or made worse by Neurontin usage."	<ul> <li>Foundation, insufficient facts or data, unreliable principles and methods (FRE 702)</li> <li>Foundation, insufficient bases for opinion (FRE 703)</li> </ul>	Defendant's identical objections have previously been overruled by Judge Saris in her Daubert opinion.
¶ 10 – "Roughly speaking, Richard Smith was a 5 on a 10 point scale for suicide risk."	<ul> <li>Foundation, insufficient facts or data, unreliable principles and methods (FRE 702)</li> <li>Foundation, insufficient bases for opinion (FRE 703)</li> </ul>	Defendant's identical objections have previously been overruled by Judge Saris in her Daubert opinion.
¶ 10 – "Richard Smith also possessed numerous personal characteristics that are protective from suicide."	<ul> <li>Foundation, insufficient facts or data, unreliable principles and methods (FRE 702)</li> <li>Foundation, insufficient bases for opinion (FRE 703)11</li> </ul>	Defendant's identical objections have previously been overruled by Judge Saris in her Daubert opinion.
¶ 11 – "This change in behavior or character is typical of drug-induced suicides."	<ul> <li>Irrelevant (FRE 401, 402)</li> <li>Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury (FRE 403)</li> <li>Improper propensity evidence (FRE 404(b))</li> <li>Not helpful to trier of fact (FRE 702)</li> </ul>	Defendant's identical objections have previously been overruled by Judge Saris in her Daubert opinion.

Testimony	Objection	Response
¶ 11 – "That is, Neurontin made Richard's depression much worse."	facts or data, unreliable principles and methods (FRE 702)  • Foundation, insufficient bases for opinion (FRE 703)	Defendant's identical objections have previously been overruled by Judge Saris in her Daubert opinion.
All of ¶ 13, entitled "Neurontin was a Substantial Contributing Factor in or Cause of Richard Smith's Suicide."12	<ul> <li>Foundation, insufficient facts or data, unreliable principles and methods (FRE 702)</li> <li>Foundation, insufficient bases for opinion (FRE 703)</li> </ul>	Defendant's identical objections have previously been overruled by Judge Saris in her Daubert opinion.
¶ 13 – "As a result of this process, commonly referred to as a 'differential diagnosis,' I conclude that Neurontin was a significant contributing factor in or cause of Richard Smith's suicide. Thus, in terms of differential diagnosis, Richard Smith's taking Neurontin was the coup de grace which caused his suicide. It was the 'trigger' or acute factor that potentiated, induced, or made worse the other suicide risk factors. I believe that gabapentin pushed Richard Smith over the edge. He changed dramatically after taking Neurontin. Gabapentin was the trigger that destroyed Richard Smiths's considerable prior ability to cope with life's problems and to fend off suicide." (emphasis in original).	<ul> <li>Foundation, insufficient facts or data, unreliable principles and methods (FRE 702)13</li> <li>Foundation, insufficient bases for opinion (FRE 703)</li> </ul>	Defendant's identical objections have previously been overruled by Judge Saris in her Daubert opinion.

Testimony	Objection	Response
¶ 13, n.11 – "All that is required is that Neurontin was one of the causes of Richard Smith's suicide, not the only cause. It was a necessary, but not sufficient condition for his suicide."	• Improper expert testimony regarding legal standard (FRE 702)	Testimony properly reflects the law in the state of Tennessee.
¶ 13, n.15 – "Smith likely did become more impulsive as a result of Neurontin causing a serotonergic dysfunction."	<ul> <li>Foundation, insufficient facts or data, unreliable principles and methods (FRE 702)</li> <li>Foundation, witness lacks knowledge, skill, experience, training, or education sufficient to render opinion (FRE 702)14</li> </ul>	Defendant's identical objections have previously been overruled by Judge Saris in her Daubert opinion.
Unnumbered paragraph called "Disclosure" – statement regarding the <i>types</i> of prescription drug cases in which he has testified, <i>i.e.</i> "in which Plaintiffs have alleged that a prescription psychiatric drug has caused a suicide."	<ul> <li>Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury (FRE 403)</li> <li>Improper propensity evidence (FRE 404(b)) Not helpful to trier of fact (FRE 702)</li> </ul>	Relevance & Bias: Disclosure statement goes directly to whether or not Dr. Maris is biased for plaintiffs or against pharmaceutical companies.

Dated: May 13, 2010 Respectfully submitted,

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#### **CERTIFICATE OF SERVICE**

I hereby certify that on this the 13th day of May, 2010, I electronically filed the foregoing document with the Clerk of the Court, United States District Court for the Middle District of Tennessee, using the CM/ECF system. True and correct copies of the foregoing documents are being served via the Court's CM/ECF system on the following:

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